

REMARKS

This Amendment is submitted in reply to the non-final Office Action dated December 30, 2009. No fee is due in connection with this Amendment. The Director is authorized to charge any additional fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 3712036-00745 on the account statement.

Claims 1-8, 12-16, 18-21, 31-33, 35-37 and 39-40 are pending in this application. Claims 9-11, 17, 22-30, 34 and 38 were previously canceled without prejudice or disclaimer. In the Office Action, Claims 1-8, 12-21, 31-33, 35-37 and 39-40 are rejected under 35 U.S.C. §103. In response, Claims 1, 4-6, 18-21 and 39-40 have been amended. The amendments do not add new matter. At least in view of the amendments and/or for the reasons set forth below, Applicant respectfully submits that the rejection should be withdrawn.

Applicant notes that Claims 19-21 and 39-40 have been amended solely for clarification purposes to reflect the amendments to Claims 1, 4-6 and 18. The amendments do not add new matter and are supported in the Specification at, for example, pages 1-2, paragraph 14.

In the Office Action, Claims 1-8, 12-21, 31-33, 35-37 and 39-40 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,380,252 B1 to De Simone ("*De Simone*"), U.S. Patent No. 6,063,820 to Cavazza ("*Cavazza I*"), U.S. Patent No. 6,348,495 B1 to Cavazza et al. ("*Cavazza II*"), U.S. Patent Publication No. 2002/0077349 A1 to Hamilton ("*Hamilton I*"), U.S. Patent Publication No. 2003/0060503 A1 to Hamilton ("*Hamilton II*") and U.S. Patent No. 6,503,506 B1 to Germano ("*Germano*"). In response, Applicant has amended Claims 1, 4-6 and 18. In view of the amendments and/or for at least the reasons set forth below, Applicant respectfully submits that the cited references are deficient with respect to the present claims.

Currently amended independent Claims 1 and 4-5 recite, in part, a method for the stimulation of the lipid metabolism in the skin of an animal or a human comprising administering an ingestible composition comprising L-carnitine, vitamin C, vitamin E, grape seed extract and cysteine, wherein the amount of L-carnitine administered daily is from about 1 mg to about 1 g per kg of body weight and the amount of vitamin C administered daily is from about 0.025 mg to about 250 mg per kg of body weight.

Similarly, currently amended independent Claim 6 recites, in part, a method for making an ingestible composition for the stimulation of the lipid metabolism in the skin of an animal or a human being, comprising the step of using L-carnitine, vitamin C, vitamin E, grape seed extract and cysteine to make the composition, wherein the amount of L-carnitine administered daily is from about 1 mg to about 1 g per kg of body weight and the amount of vitamin C administered daily is from about 0.025 mg to about 250 mg per kg of body weight.

Currently amended independent Claim 18 recites, in part, an ingestible composition selected from the group consisting of a medicament, a food, a functional food, a nutritional complete pet or human food, and a dietary supplement comprising L-carnitine, vitamin C, vitamin E, grape seed extract and cysteine, wherein the amount of L-carnitine administered daily is from about 1 mg to about 1 g per kg of body weight and the amount of vitamin C administered daily is from about 0.025 mg to about 250 mg per kg of body weight. . The amendments do not add new matter. The amendments are supported in the Specification at, for example, pages 1-2, paragraph 14; page 2, paragraphs 18-22; page 4, paragraph 55; page 5, paragraphs 57-63; Table 1.

Conventional methods of improving skin involve the use of topical formulations that merely treat the symptoms of skin conditions or ingestible compositions which contain rare and expensive starting materials of plant or animal origin. See, Specification, page 1, paragraphs 3-4. Therefore, the present claims provide an ingestible composition comprising L-carnitine, vitamin C, vitamin E, grape seed extract and cysteine and methods of administering or using the same. The claimed combination of compounds demonstrates a protective activity with respect to inflammatory skin diseases, helps to avoid dermatitis, and increases the lipid secretion in sebum. See, Specification, page 2, paragraph 18; page 5, paragraphs 57-63; Table 1. In contrast, Applicant respectfully submits that the cited references are deficient with respect to the present claims.

For example, even if combinable, *De Simone*, *Cavazza I*, *Cavazza II*, *Hamilton I* and *Hamilton II* fail to disclose or suggest ingestible compositions comprising grape seed extract or methods of administering or using the same as recited, in part, by independent Claims 1, 4-6 and 18. The Patent Office asserts that *De Simone* teaches a method for treating diseases related to IGF-1 comprising administering a composition including L-acetylcarnitine, coenzyme Q10,

vitamin E and Se-L-methionine. See, Office Action, page 3, lines 6-21; page 4, lines 1-2. However, nowhere does *De Simone* teach or suggest administering grape seed extract, nor does the Patent Office cite support for such claimed element.

The Patent Office asserts that *Cavazza I* discloses the use of L-carnitine to treat intestinal disorders and *Cavazza II* teaches the use of alkanoyl-L-carnitine, acetyl-L-carnitine and/or propionyl-L-carnitine as a medicinal food for diabetics. See, Office Action, page 4, lines 3-22; page 5, lines 1-2. However, neither *Cavazza I* nor *Cavazza II* teaches or even suggests the use of grape seed extract.

The Patent Office asserts that *Hamilton I* teaches administering a combination of L-carnitine and thioctic acid to treat age-related vision losses. See, Office Action, page 5, lines 3-8. The Patent Office further asserts that *Hamilton II* discloses a composition for senior pets comprising carnitine, α -lipoic acid and optionally coenzyme Q and/or creatine. See, Office Action, page 5, lines 8-17. However, nowhere do *Hamilton I* or *Hamilton II* teach or even suggest the use of grape seed extract.

The Patent Office asserts that *Germano* discloses a nutritional supplement for treating chronic debilitating diseases such as HIV/AIDS comprising an orally administrable superoxide dismutase ("SOD") in combination with coenzyme Q10, D-ribose and L-carnitine. See, Office Action, page 5, lines 18-22; page 6, lines 1-4. Nowhere does *Germano* teach or even suggest administering grape seed extract. As such, even if combinable, the combination of *De Simone*, *Cavazza I*, *Cavazza II*, *Hamilton I*, *Hamilton II* and *Germano* fails to disclose or suggest ingestible compositions comprising grape seed extract or methods of administering or using the same in accordance with the present claims.

Moreover, one of ordinary skill in the art would have no reason to combine the teachings of *De Simone*, *Cavazza I*, *Cavazza II*, *Hamilton I*, *Hamilton II* and *Germano* to arrive at the present claims. The Patent Office asserts that it would have been obvious to one of ordinary skill in the art to combine the teachings of *De Simone*, *Cavazza I*, *Cavazza II*, *Hamilton I*, *Hamilton II* and *Germano* to develop non-invasive treatments for various medical problems because the compositions of the cited references also comprise the natural compounds disclosed in the instant claims. See, Office Action, page 6, lines 5-12. However, "[t]he mere fact that references can be

combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art.” See, M.P.E.P. §2143.01(III) (2009).

De Simone is entirely directed to the use of L-acetylcarnitine to induce the production of IGF-1 and treat cytological disorders or diseases related to IGF-1 such as neuropathies of the optic and olfactory nerves, paralysis and osteoporosis. See, *De Simone*, Title; Abstract; column 1, lines 15-34; column 2, lines 44-49. *De Simone* is entirely unconcerned with treating skin disorders or stimulating the lipid metabolism in the skin to increase the lipid secretion in sebum and fails to even mention the terms “skin,” “lipid metabolism” or “sebum.”

In contrast, *Cavazza I* is directed to a medical food for diabetics comprising γ -linolenic acid and an L-carnitine derivative. See, *Cavazza I*, Title; Abstract; column 2, lines 17-26. *Cavazza I* teaches that its medical food by-passes the enzyme blockade that results in the inadequate conversion of linoleic acid into γ -linolenic acid. See, *Cavazza I*, column 2, lines 17-26. *Cavazza II* is directed to the use of alkanoyl L-carnitine to treat inflammatory bowel diseases. See, *Cavazza II*, Title; Abstract; column 1, lines 11-20; column 2, lines 62-67; column 3, lines 1-7. *Cavazza I* and *Cavazza II* are entirely unconcerned with treating skin disorders or stimulating the lipid metabolism in the skin to increase the lipid secretion in sebum.

Hamilton I is directed to the administration of carnitine and lipid acid to promote healthy mitochondria and treat age-related vision impairment. See, *Hamilton I*, Title; Abstract; page 1, paragraph 2; pages 2-3, paragraph 23. *Hamilton II* is directed to nutritional supplements for mature pets comprising α -lipoic acid and carnitine. See, *Hamilton II*, Title; Abstract; page 1, paragraph 2. *Germano* is entirely directed to a nutritional supplement for treating chronic debilitating diseases such as HIV/AIDS comprising SOD, whey, glutamine, coenzyme Q10 and L-carnitine. See, *Germano*, Title; Abstract. *Hamilton I*, *Hamilton II* and *Germano* are entirely unconcerned with treating skin disorders or stimulating the lipid metabolism in the skin.

One of ordinary skill in the art would understand that the objectives and anatomical effects resulting from the administration of the compounds of the cited references are entirely distinguishable. As such, one of ordinary skill in the art would have had no reason to combine the teachings of *De Simone*, *Cavazza I*, *Cavazza II*, *Hamilton I*, *Hamilton II* and *Germano* to arrive at the present claims with a reasonable expectation of success because the references are directed to different problems in different fields of endeavor.

Furthermore, even if a *prima facie* case of obviousness has been established, Applicant respectfully submits that the present claims are not obvious over the cited references because the Specification demonstrates unexpected results for the claimed combination of compounds. For example, the Specification discloses an experiment in which mice were fed standard Diets A and B consisting of proteins, fat, carbohydrates and cellulose; comparative Diet C consisting of Diet A in addition to vitamin C, vitamin E, grape seed extract and cysteine; Diet D comprising Diet A in addition to L-carnitine, vitamin C, vitamin E, grape seed extract and cysteine; and comparative Diet E consisting of Diet A and L-carnitine. See, Specification, page 4, paragraph 55.

Table 1 demonstrates that the incidence of dermatitis in the group of mice fed Diet D including both L-carnitine and vitamin C, vitamin E, grape seed extract and cysteine was 0.00, whereas the incidence of dermatitis in the groups fed standard Diets A and B was 0.10 and 0.11, respectively. See, Specification, page 5, Table 1. The incidence of dermatitis in the groups of mice fed Diets C or E including either L-carnitine or vitamin C, vitamin E, grape seed extract and cysteine was 0.16. See, Specification, page 5, Table 1. Thus, Table 1 demonstrates that a diet comprising L-carnitine in addition to vitamin C, vitamin E, grape seed extract and cysteine results in a significantly lower incidence of dermatitis compared to diets which do not include the claimed combination. See, Specification, page 5, paragraphs 57-63; Table 1. As such, the claimed combination of compounds would not have been obvious to one of ordinary skill in the art based on the disclosures of *De Simone*, *Cavazza I*, *Cavazza II*, *Hamilton I*, *Hamilton II* and *Germano*.

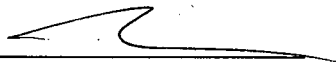
Accordingly, Applicant respectfully requests that the rejection of Claims 1-8, 12-21, 31-33, 35-37 and 39-40 under 35 U.S.C. §103(a) to *De Simone*, *Cavazza I*, *Cavazza II*, *Hamilton I*, *Hamilton II* and *Germano* be withdrawn.

For the foregoing reasons, Applicant respectfully requests reconsideration of the above-identified patent application and earnestly requests an early allowance of the same. In the event there remains any impediment to allowance of the claims which could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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